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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/ Counterclaim-Defendant

vs.

INTUITIVE SURGICAL, INC.,

Defendant/ Counterclaimant.

Case No.: 3:21-cv-03496-VC

INTUITIVE SURGICAL, INC.'S MOTION TO EXCLUDE TESTIMONY OF JEAN SARGENT

Hearing Date: June 8, 2023
Hearing Time: 1:00 p.m.
Hearing Place: Courtroom 4

Judge: The Honorable Vince Chhabria

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, at 1:00 p.m., or as soon thereafter as available, in the courtroom of the Honorable Vince G. Chhabria, located at 450 Golden Gate Avenue, Courtroom 4, 17th Floor, San Francisco, CA 94102, Defendant/Counterclaimant Intuitive Surgical, Inc. will and hereby does move for an order excluding certain testimony of Jean Sargent, proffered as an expert witness for Plaintiff/Counterclaim-Defendant Surgical Instrument Services Company, Inc.

This Motion is based on this Notice of Motion, the Memorandum of Points and Authorities, the accompanying Declaration of Andrew Lazerow and attached exhibits, any reply or other supplemental briefing and/or evidence submitted by Intuitive Surgical, Inc., and the oral argument of counsel.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND STATEMENT OF ISSUE

Defendant/Counterclaimant Intuitive Surgical, Inc. ("Intuitive") moves pursuant to Rule 702 of the Federal Rules of Evidence to exclude certain opinions of Jean Sargent ("Sargent"), a witness proffered by Plaintiff/Counterclaim-Defendant Surgical Instrument Service Company, Inc. ("SIS") to opine as an expert on "procurement of instrument repair services" from Group Purchasing Organizations ("GPOs") and "hospital practices regarding Food and Drug Administration ('FDA') approvals and clearance for instrument repair services." Lazerow Dec. Ex. 1 (Sargent Report, Dec. 2, 2022) ¶ 19. Sargent offers three opinions, none of which withstands scrutiny under Rule 702. Specifically, Intuitive moves to exclude the following opinions:

1. Hospitals "do not consider whether FDA device approvals and clearances such as 510(k) have been obtained for servicing and repair services of instruments that are owned by the hospital," *id.* ¶ 22;
2. Hospitals participating in SIS's EndoWrist reset program would achieve an instrument collection rate of "approximately 75%," *id.* ¶ 56; and
3. SIS would have achieved customer "conversion" or "penetration" rates among member hospitals of one GPO (Vizient) of "30% by the end of the first year [of

> offering its EndoWrist reset service], 70% by the end of the second year after the service is introduced, and 70%–80% thereafter," *id.* ¶¶ 23, 57.[1]

The CPA retained by SIS to estimate its purported damages (Richard Bero) builds his entire damages claim off of Sargent's second and third opinions. As shown in the motion to exclude Mr. Bero's damages' estimates, Sargent's fatally-flawed opinions infect SIS's damages' claim.

Sargent's opinions are inadmissible for the following reasons. *First*, Sargent's first opinion is irrelevant and would, at best, simply confuse the jury. There is no disputed issue as to whether a hospital may "service and repair" its own devices without first obtaining FDA clearance. No one contends that FDA clearance is required if a third party engages in activities that constitute service or repair. The fundamental question in this case, however, is whether modifying EndoWrists to circumvent their use counters is "repair" or "servicing" (for which no FDA clearance is required) or is "remanufacturing" (which cannot be performed lawfully without FDA clearance). Sargent has no basis to opine on that question and does not purport to do so. She does not claim to be an expert in repair or remanufacturing of EndoWrists (or any other medical device) or in FDA's regulation of medical devices. It is thus unsurprising that she does not opine on whether SIS's activities would be properly characterized as "repair" or "remanufacturing." In fact, Sargent admits that she does not even know the difference between "repair," "servicing," and "remanufacturing," and repeatedly lumped them together during her deposition. Her opinion thus does not fit with the issues in this case.

Second, Sargent's second opinion – that hospitals would "collect" EndoWrists for SIS's service at a rate that "would likely be at the high end of general industry collection rates for instrument repairs, which in [Sargent's] experience would be approximately 75%," *id.* ¶ 56 – is unreliable because it is not based on any methodology, analysis, industry statistics or information, literature, or facts from the record. Sargent admits that she is not relying on any other medical device collection program in support of her opinion and that she did not even know the "collection rate" for the one "program" involving

[1] For the avoidance of doubt, Intuitive reserves the right to raise additional objections to Sargent's testimony at a later date. This brief focuses on key issues fit for resolution at this stage of the case.

collection of EndoWrists that she had some involvement in as a consultant before this case. Such an unsupported *ipse dixit* opinion is too unreliable to be admissible.

Third, Sargent's final opinion – that certain percentages of hospitals of one Group Purchasing Organization ("GPO") would "convert" to SIS's EndoWrist modifications (*Id.* ¶¶ 23, 57) – is both unhelpful and unreliable. A GPO negotiates with medical product and service vendors to provide bulk pricing or other purchasing incentives to its members. Even though Sargent admits that member hospitals are not required to purchase anything as a result of GPO-negotiated contracts, Sargent predicts that SIS's contract with one GPO – Vizient Inc. – would have resulted in 30% of the members of that GPO signing up to modify EndoWrists within one year of offering the service, 70% within the second year, and 70%–80% thereafter. *Id.* ¶ 57. Again, Sargent did not develop any methodology or cite any industry statistics or information, literature, or facts from the record in support of this opinion. For example, Sargent did not know that SIS was relying entirely on a third party for its service, had no idea how many member hospitals Vizient or SIS contacted about the service, and had no idea how many modified EndoWrists SIS actually sold or the number of hospitals to which SIS made any sales. She does not know whether any other company offered a comparable service to SIS's program. At bottom, Sargent provides no basis or reasoning as to why any particular Vizient members would purchase anything from SIS, and Sargent admits that her "opinion" about SIS's expected performance with Vizient members was limited to that GPO and could not be extrapolated to other GPOs or hospitals who are not part of any GPO. Sargent's opinion amounts to an unreliable *ipse dixit* assertion that is not admissible under *Daubert*.

II. STATEMENT OF FACTS

Sargent holds herself out as a consultant with experience in healthcare sterile processing and materials management for hospitals. *Id.* Ex. 1 ¶¶ 2, 9, 14. Before becoming a consultant, Sargent worked for a handful of hospitals and one GPO in roles primarily focused on financial cost management. *Id.* § 1. She does not have a bachelor's or advanced degree, and has no medical training or experience administering surgical operating rooms. *See generally id.* § 1; Lazerow Dec. Ex. 5 (Def.'s Ex. 231.

Sargent LinkedIn); Lazerow Dec. Ex. 2 40:17–19. Sargent has never worked at a medical device manufacturer or medical device repair or remanufacturing company, and she has no medical device sales experience. *Id.* Ex. 2 82:6–83:1. She has never worked for the FDA and has never worked with the FDA on projects relating to the da Vinci Surgical System or EndoWrists. *Id.* 84:13–25.

SIS retained Sargent to offer three opinions in this matter. *First*, she opines that hospitals "do not consider whether FDA device approvals and clearances such as 510(k) have been obtained for servicing and repair services of instruments that are owned by the hospital." Lazerow Dec. Ex. 1 ¶ 22. At deposition, Sargent clarified that this opinion only applies to hospitals that are members of a certain GPO: Vizient Inc. Lazerow Dec. Ex. 2 90:3–22. Sargent does not identify (or even know) the activities that constitute "servicing or repair services," but instead defines servicing and repair services based "simply on the fact that a hospital sends . . . instruments out to a third-party." *Id*. 93:5–14. Sargent also does not define "remanufacturing" or her own term of "refurbishment." *Id.* 57:16–58:24. In fact, she uses all of these terms interchangeably, testifying that her opinions apply whether hospitals seek these "servicing and repair services" from "manufacturers or remanufacturers or refurbishers, whatever they might be." *Id.* 65:15–66:7. Unsurprisingly, Sargent testified that she does not offer an opinion, and is not qualified to opine on, whether any activity qualifies as "repair" or "remanufacturing" under FDA regulations. *Id.* 87:20–24, 88:21–89:2. But Sargent admitted that hospitals consider the presence or absence of FDA clearance when a third party is engaged in activities that require such clearance. *Id.* 70:3–23.

Sargent assumes that when an instrument is sent to a third party, the third party is "doing what [it is] supposed to be doing to refurbish, remanufacture, repair that product," but she admitted that she would not know what it is that third parties are "supposed to be doing" unless she investigated that (which she has not done). *Id.* 93:15–94:19. Sargent does not know what SIS or any third party has actually done to modify EndoWrists to reset their use counters. *Id.* 124:19–127:23. Sargent also does not know whether SIS ever had the original specifications for EndoWrists, and thus accepted SIS's claim that it returns an EndoWrist to its original specifications "at face value." *Id.* 134:2–135:15.

Second, Sargent opines that hospitals participating in SIS's program at one GPO (Vizient) would achieve an instrument collection rate of "approximately 75%." Lazerow Dec. Ex. 1 ¶ 56. Sargent's estimate applies only to Vizient member hospitals and cannot be extrapolated to any other hospitals. Lazerow Dec. Ex. 2 225:25–226:20, 308:22–309:3. Sargent admits that she considered no industry information, literature, or facts from the record to support her view that there is such a thing as a "general industry collection rate" or what any such rate might be. Lazerow Dec. Ex. 1 ¶ 56; Lazerow Dec. Ex. 2 228:11–229:21. And Sargent has no experience with, or knowledge of, collection rates for EndoWrists at any hospital. *Id.* Ex. 2 298:19–299:3, 307:11–15. She does not even know the "collection rate" for the one hospital for which she had some personal involvement. In 2019, Sargent introduced SIS to Marin Health, a hospital with which she was consulting at the time. *Id.* 106:2–107:7; Lazerow Dec. Ex. 6 (Def.'s Ex. 232 (SIS000445)) at SIS000447. Marin used SIS to modify a handful of its EndoWrists, but Sargent never saw the process by which SIS collected EndoWrists from Marin; nor did she know how many EndoWrists in Marin's inventory were actually collected by SIS. Lazerow Dec. Ex. 2 215:4–18, 307:5–10.

Third, Sargent opines on the rates at which Vizient member hospitals would have "converted" to SIS's EndoWrist modification service: "30% by the end of the first year [of offering the reset service], 70% by the end of the second year after the service is introduced, and 70%–80% thereafter." Lazerow Dec. Ex. 1 ¶¶ 23, 57. Sargent relies principally on the fact that SIS and Vizient entered an agreement in September 2019, but she admits that that agreement did not require Vizient members to purchase anything from SIS. Lazerow Dec. Ex. 2 195:11–196:4. Again, Sargent testified that her opinion on conversion rates only applies to Vizient member hospitals, and cannot be extrapolated to non-member hospitals. *Id.* 308:18–309:3. She admitted that she has not done anything to investigate whether SIS would achieve her estimated penetration rates at non-Vizient member hospitals. *Id.*

Sargent admitted at deposition that member hospitals are free to decide whether they will purchase any service offered by SIS. *Id.* 192:23–193:17; 195:11–196:17. She does not know how many hospitals Vizient or SIS contacted about this program or the number of sales personnel available to

Vizient and SIS to contact hospitals about the program. *Id.* 199:12–25, 232:22–233:2. She has "no idea" how many reset EndoWrists SIS sold or how many hospitals SIS sold to. *Id.* 248:2–16. Sargent did not know whether SIS's service was exclusive, whether any other company offered a service to modify EndoWrists comparable to SIS's service, or whether any company had received clearance from the FDA to modify any EndoWrists to add additional uses. *Id.* 26:19–27:2, 253:22–254:17; Lazerow Dec. Ex. 1 ¶ 45.

Sargent's estimates of purported collection and conversion rates are key assumptions underlying SIS's damages claim. Richard Bero, the CPA SIS retained to estimate its damages, used her rates to arrive at the number of EndoWrists SIS would have purportedly modified in the but-for world. Bero did that even though Sargent admitted that there is no way based on her report "to determine how many EndoWrists would be collected by SIS from Vizient members," she is not offering an opinion on collection rates at non-Vizient members, and she did not investigate whether non-Vizient members would achieve the rates she posits for Vizient members. *See* Lazerow Dec. Ex. 3 (Bero Report, Dec. 2, 2022) § XIV(E)(1)(a)(v), Schedule 2.2; Lazerow Dec. Ex. 4 (Updated Bero Report Schedules, Feb. 25, 2023) Schedule 2.2; Lazerow Dec. Ex. 2 224:10–15, 226:16–20, 308:18–309:3. Moreover, Bero uses Sargent's numbers to arrive at SIS's expected number of modifications of all EndoWrists, even though Sargent admits that her estimates are limited to hospitals that have S/Si da Vinci systems and do not include X/Xi EndoWrists. *See* Lazerow Dec. Ex. 4 Schedule 2.2; Lazerow Dec. Ex. 2 209:10–211:13 ("Q. So is there any particular time in the future that you assumed that there would be X and Xi EndoWrists collected? A. No."); *id.* 232:7–14 ("I would say 70 to 80 percent of the hospitals that have an S or Si would participate.").

III. ARGUMENT

SIS cannot meet its burden to establish the admissibility of Sargent's opinions. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n. 10 (1993) (stating that issues related to the admissibility of evidence "should be established by a preponderance of proof"). Expert witness testimony must (1) be from a qualified expert; (2) be helpful to the factfinder; (3) be based on sufficient

facts or data; (4) rely on reliable principles and methods; and (5) represent reliable application of those principles and methods to the facts of the case. Fed R. Evid. 702. The Court's "gatekeeping" role requires evaluating both the reliability of the expert's methods and the connection between their conclusions and the facts on which those conclusions are based. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

A. Sargent's Opinion Regarding Vizient Member Hospitals' Concern With FDA Clearance for Hospital-Owned Instruments Is Irrelevant.

This opinion is irrelevant because it has no valid connection to a pertinent inquiry the jury must decide. *See Daubert*, 509 U.S. at 591 ("Rule 702 further requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' This condition goes primarily to relevance."); *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) ("Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry.") (quoting *United States v. Sandoval-Mendoza*, 472 F.3d 645, 654 (9th Cir. 2006)).

Sargent explicitly conceded that she has no opinion on the key question of whether modifying an EndoWrist to extend the number of approved uses constitutes "remanufacturing" (which requires FDA clearance) or "servicing/repair" (which does not). Sargent could not even offer definitions of these terms and used them interchangeably throughout her deposition. The fact that a hospital sends an instrument to a third party tells you nothing about what activity the third party actually performs on the instrument. Thus, whether a hospital "cares" about the lack of FDA clearance for a "repair" or "service" has no bearing on what a hospital would do if SIS's activity qualified as remanufacturing. On that question, Sargent admits that some Vizient member hospitals ***would*** care if SIS must have 510(k) clearance to modify EndoWrists to allow for additional uses beyond their predetermined use limit. (SIS did not have such clearance.) Lazerow Dec. Ex. 2 68:18–23.

Sargent has no knowledge about several key facts that an expert would need to understand to assist the jury in understanding the evidence. Sargent does not know how SIS modifies EndoWrists in order to extend the number of approved lives. Sargent discloses nothing in her report or in her "materials cited" that suggests she knows what SIS did to purportedly return EndoWrists to their

original specifications. Instead, Sargent admitted at her deposition that she took SIS's claim that it returned EndoWrists to their original specifications "at face value," even though she does not know whether SIS even had the original specifications for EndoWrists. *Id.* 134:2–135:15. Even if she knew something about SIS's process, she cannot provide the jury with any sort of comparison to repair or remanufacturing processes for other instruments because she does not know what any third party does with any instrument that a hospital sends to them.

Sargent's first opinion simply provides nothing of use to the jury.

B. Sargent's Opinion Regarding Expected Rates of "Collection" of Used Instruments from Vizient Member Hospitals Is Unreliable.

Sargent's opinions on "collection" rates are too unreliable to be admissible because Sargent does not base this opinion on any methodology, analysis, or industry information, and fails to consider evidence of Intuitive's efforts to collect used instruments.

First, Sargent has no experience with collection of EndoWrists at any hospital. She has no experience at all with SIS's program at Vizient member hospitals. Although she was consulting with a non-member hospital (Marin Health) at the time it was using SIS to modify EndoWrists, Sargent never observed the EndoWrist collection process and does not know how many EndoWrists SIS collected from that hospital. Moreover, Sargent provides no explanation of the "general industry collection rates" on which she purportedly relies. She considered no industry statistics, no literature, and no facts from the record to suggest that "general industry collection rates" even exist, much less what they might be. Lazerow Dec. Ex. 1 ¶ 56. Sargent purportedly bases her assertion of a 75% instrument collection rate on experience with "general industry collection rates for instrument repairs," but she admits that she does not know the collection rates of any instrument collection programs. Lazerow Dec. Ex. 2 228:11–229:10, 307:5–15. Moreover, her "collection rate" only applies to Vizient member hospitals and she did nothing to determine whether non-Vizient members would achieve similar collection rates. In short, Sargent fails to demonstrate how her purported experience supports her opinion about EndoWrist collection among Vizient member hospitals. She thus offers nothing more than speculation. *See Aya Healthcare Servs., Inc. v. AMN Healthcare, Inc.*, 2020 WL 2553181, at *4 (S.D. Cal. May, 20, 2020)

(Expert knowledge "requires more than a subjective belief or an unsupported speculation." (citing *Daubert*, 509 U.S. at 593)).

Second, Sargent's purported reliance on "general industry collection rates" is particularly problematic because she ignores record evidence that is inconsistent with her opinion. Sargent did not consider that ***Intuitive itself*** experienced challenges with instrument collection when it evaluated whether to pursue programs to collect expired EndoWrists, return them to like-new condition, and re-sell them to hospitals. *See* Lazerow Dec. Ex. 7 (Morales Nov. 11, 2022 Dep.) 172:4–173:20 (explaining the logistical challenges of instrument collection that impeded Intuitive's "refurbishment" pilot project); Lazerow Dec. Ex. 8 (Tourand Nov. 4, 2022 Dep.) 37:14–21, 44:9–20 (explaining that "Project Refurbished Instruments" never became an "actual commercial program" in France because the low yield of collected instruments used at French hospitals meant the program "didn't make sense to actually complete"). Sargent did not consider that Intuitive's pilot program experienced instrument collection rates at individual participating hospitals as low as 4% and never as high as Intuitive's targeted rate of 70%. *See* Lazerow Dec. Ex. 9 (Intuitive-00626597) at Intuitive-00626604. Sargent does not even attempt to account for this evidence that contradicts her opinion. Expert opinions that ignore critical facts are "so incomplete as to be inadmissible as irrelevant." *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d 966, 973 (C.D. Cal. 2012) (quoting *Hemmings v. Tidyman's Inc.*, 285 F.3d 1174, 1188 (9th Cir. 2002)).

C. Sargent's Opinion Regarding Expected "Conversion" of Vizient Member Hospitals to the Use of SIS's Modified EndoWrists Is Unreliable.

Sargent's estimates of the percentage of Vizient member hospitals that would permit SIS to modify their EndoWrists are also too unreliable to be admissible. *First*, Sargent offers no methodology, literature, data, or relevant experience demonstrating why SIS would make any level of sales to any hospital. Her opinion should be excluded on this basis alone. *See Adkins v. Facebook, Inc.*, 424 F. Supp. 3d 686, 693–94 (N.D. Cal. 2019) (excluding expert testimony that was not based in "sufficient facts or data," was not "the product of reliable principles and methods," and "even accepting the principles and methods," was "not reliably appl[ied] . . . to the facts of th[e] case"); *Al-Daiwa, Ltd. v.*

Apparent, Inc., 2015 WL 5304111, at *1 (N.D. Cal. Sept. 9, 2015) (Chhabria, J.) (Where it is "unclear what methods or principles [the expert] is applying to the facts of the case," "it is impossible to say that [the expert's] testimony is reliable.").

Second, she fails to demonstrate "similar penetration rates within a GPO" for any of the categories of instruments she identifies in her report ("electrophysiology diagnostic catheters, cables, endo shears, trocars, and laparoscopic instruments"). Lazerow Dec. Ex. 1 ¶ 57. Because Sargent does not even assert (much less establish) that these categories of instruments or the activities associated with them are comparable to EndoWrists and SIS's business, SIS cannot meet the requirement to show how Sargent's experience "leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Ev. 702 (Advisory Committee Notes, 2000 Amendments); *see Caldwell v. City of San Francisco*, 2021 WL 1391464, at *3 (N.D. Cal. Apr. 13, 2021).

Third, even if she had some relevant experience, industry information, or literature, Sargent would be unable to apply any of that "reliably to the facts of the case" because she has no knowledge of key facts related to SIS's business or any other third party engaged in modifying EndoWrists. *See United States v. Redlightning*, 624 F.3d 1090, 1111 (9th Cir. 2010) (quoting Fed. R. Civ. P. 702 (2010)). Sargent mistakenly thought that SIS is the only company that modified EndoWrists. Lazerow Dec. Ex. 2 97:12–18. She had not even heard of the company, Rebotix Repair, that actually performed the modification of EndoWrists for SIS and for whom SIS was simply a distributor. *Id.* 54:18–21. Perhaps most tellingly, Sargent ignores SIS's actual sales experience entirely, and thus does not even attempt to explain how her estimates can stand in the face of the following facts:

- Only ***six*** hospitals used SIS to modify no more than 42 EndoWrists. Lazerow Dec. Ex. 2 248:2–16; Lazerow Dec. Ex. 3 § VI(E), Schedule 14.0.
- The ***three*** customers of SIS who were Vizient members accounted for less than 1% of the population of total Vizient members. *See* Lazerow Dec. Ex. 2 192:18–22 (estimating that Vizient has over 4,000 members); Lazerow Dec. Ex. 3 Schedule 14.0; Lazerow Dec. Ex. 10 (Johnson 30(b)(6) Dep.) 116:1–9 (identifying three Vizient members for whom SIS facilitated EndoWrist resets).
- ***None*** of the three Vizient members who used SIS did so pursuant to the Vizient-SIS contract because their transactions with SIS occurred before that contract was executed on September

15, 2019. *See* Lazerow Dec. Ex. 3 § X(A)(2), Schedule 14.0; *cf.* Lazerow Dec. Ex. 10 116:1–9.

Quite simply, there is nothing in the record to support Sargent's opinion that SIS would have sold to 30% of Vizient member hospitals within the remaining six months of its first year of service, much less to 70% of all Vizient members within the following year or any year thereafter.

Without any basis in fact, replicable methodology, or applicable experience, Sargent's "opinion" about hospitals' willingness to "default" to using SIS's service and SIS's expected "penetration" rates are based entirely on "the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146. There is simply "too great an analytical gap between the data and the opinion proffered" for Sargent's testimony to be reliable or relevant to the jury, meaning it must be inadmissible. *Id.*

IV. CONCLUSION

For the foregoing reasons, the Court should grant this Motion and exclude Sargent's opinions that: (1) hospitals do not consider whether FDA device approvals and clearances such as 510(k) have been obtained for servicing and repair services of instruments that are owned by the hospital; (2) hospitals participating in SIS's EndoWrist reset program would achieve an instrument collection rate of approximately 75%; and (3) SIS would have achieved customer "conversion" or "penetration" rates among member hospitals of one GPO (Vizient) of "30% by the end of the first year [of offering its EndoWrist reset service], 70% by the end of the second year after the service is introduced, and 70%–80% thereafter."

DATED: March 23, 2023

By: */s/ Kathryn E. Cahoy*
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